DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

JAN - 7 2010

Medline Industries, Inc.
% Mr. Matt Clausen
Regulatory Affairs
One Medline Place
Mundelein, Illinois 60060-4486

Re: K093349
Trade/Device Name: Medline Curad Oil Emulsion Dressing
Medline Curad Xeroform Petrolatum Dressing
Medline Curad Petrolatum Gauze Dressing
Regulation Number: None
Regulation Name: None
Regulatory Class: Unclassified
Product Code: FRO
Dated: December 22, 2009
Received: December 23, 2009

Dear Mr. Clausen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K093349

Device Name:

Medline Curad Xeroform Petrolatum Dressing

Indications for Use:

The intended use is as a wound dressing layer for skin graft recipient sites, newly sutured wounds, abrasions, lacerations and minor or partial thickness burns. These dressings may also be used as an initial layer for wounds with light exudates where deodorization is desired.

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K093349

Indications for Use

510(k) Number (if known): K093349

Device Name:

Medline Curad Petrolatum Gauze Dressing

Indications for Use:

These dressings are intended for use as a primary layer for donor sites, skin graft recipient sites and minor burns. These dressings may also be used as an initial layer for surgical incision sites and as a seal around tubes and drains exiting the body.

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K093349

Indications for Use

510(k) Number (if known): K093349

Device Name:

Medline Curad Oil Emulsion Dressing

Indications for Use:

These dressings are intended for use as a primary dressing in the management of light to medium draining wounds such as minor burns, abrasions and lacerations. These dressings may also be used under the care of a health care professional for heavy draining wounds such as surgical incisions, skin grafts and dermal ulcers.

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _X____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause

(Division Sign-Off)
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